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REMARKS

In the Office Action, claims 1-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,456,708 to Doan et al. in view of U.S. Patent No. 5,522,872 to Hoff.

In response thereto, claims 2, 8, and 14 have been cancelled, claims 1, 3, 7, 13, 15, and 20 have been amended, and claims 22-28 have been added. Accordingly, claims 1, 3-7, 9-13, and 15-28 are now pending. Following is a discussion of the patentability of each of the pending claims.

Independent Claim 1

Claim 1 recites an implantable lead comprising a helical fixation element extendable and retractable from a distal end of the lead. The distal end of the lead comprises (a) an inner header tube comprising an electrically conductive material that is substantially transparent fluoroscopically to allow an unobstructive fluoroscopic view of the helical fixation element, the helical fixation element is housed within the inner header tube when in a retracted position, and the inner header tube has a distal end, (b) an outer header tube comprising an electrically insulating material, the outer header tube is coaxial to the inner header tube, and (c) a distal tip collar attached to the distal end of the inner header tube, and the distal tip collar comprises a material that is substantially opaque fluoroscopically, and the distal tip collar is electrically coupled to the distal end of the inner header tube.

The Doan et al. reference is directed to providing a lead (10) with a substantially transparent fluoroscopic header tube that permits direct and rapid positional verification of a helical electrode. The lead (10) has a helix electrode (30) for piercing tissue to be stimulated (see Figure 1). A collar (30) is provided at the distal tip of the lead to facilitate fluoroscopic verification of the extension of the helix electrode relative to the lead tip during lead fixation. The collar is mounted within a recess (41) of an insulative header tube (24) adjacent the lead tip surface (26). The collar is electrically isolated

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and is secured to the header tube by means of a bonding agent such as a urethane adhesive.

The Doan et al. reference does not disclose or suggest an inner header tube housing a helical fixation element and comprising an electrically conductive material that is substantially transparent fluoroscopically to allow an unobstructive view of the helical fixation element. The Doan et al. reference discloses an electrically insulative header tube (24) that houses the helical electrode (30).

The Hoff reference discloses a lead having a sleeve (12) that joins a conductor (10) to electrode elements (17), and the electrode elements are connected to an electrode (14). The conductor and electrode elements are inserted into passages formed through the sleeve and are bonded to the sleeve surface by laser welding.

The Hoff reference does not disclose or suggest an inner header tube housing a helical fixation element and comprising an electrically conductive material that is substantially transparent to allow an unobstructive view of the helical fixation element. According to the Hoff reference, the electrode is located proximal to the sleeve. Nowhere does the Hoff reference disclose or suggest that the sleeve can house the electrode when in a retracted position.

Furthermore, it would not be obvious to combine the teachings of the Doan et al. and Hoff references to electrically couple a distal tip collar to a proximal portion of the lead because the modified Doan et al. device will not function as intended. The Doan et al. reference is directed to providing a lead with a substantially transparent fluoroscopic header tube (24) that permits direct and rapid positional verification of a helical electrode (30). It appears that the fluoroscopic view of the helical electrode (30) will be impeded by electrically coupling the collar (42) with the electrical coupling assembly (sleeve (12), conductor (10), electrode elements (17), and electrode (14)) disclosed in the Hoff reference. With such a modification, the helical electrode (30) would be housed within the electrode elements (17). According to Figure 4a, the electrode (14) and electrode elements (17) are integral such that a fluoroscopically opaque electrode (14) would necessitate a fluoroscopically opaque electrode element. As such, the

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fluoroscopically opaque electrode elements (17) may hinder the fluoroscopic view of the helical electrode (30).

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 3-6, 20, and 22-24

Claims 3-6, 20, and 22-24 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 7

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 7 is in condition for allowance.

Dependent Claims 9-12, 21, 25, and 26

Claims 9-12, 21, 25, and 26 depend from claim 7 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 13

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 13 is in condition for allowance.

Dependent Claims 15-19, 27, and 28

Claims 15-19, 27, and 28 depend from claim 13 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

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CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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